

**Ethical Considerations
for a Public Health
Response Using
Molecular HIV
Surveillance Data:**

A Multi-Stakeholder Approach

May 10 & 11, 2017, Chicago, IL

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On May 10 and 11, 2017, the Third Coast Center for AIDS Research (TC CFAR), in collaboration with Project Inform, sponsored a multi-sector stakeholder consultation in Chicago, IL, to discuss the potential benefits and drawbacks to the now-expanding use of analyses of relatedness of HIV genetic sequences (called phylogenetic analyses of HIV) as another tool for guiding public health efforts aimed at limiting HIV spread.

Phylogenetic analysis derives from HIV resistance genotyping, which has been used since the late 1990s, to guide the selection of new antiretroviral drugs following treatment failure. In the 2000s, routine genotypic testing was expanded to newly diagnosed individuals in order to rule out pre-existing HIV drug resistance before starting someone on a new antiretroviral therapy (ART) regimen. In some states, the results of this test are required to be reported to health department to monitor drug resistance, and the number of states with such reporting laws has grown in recent years. As of January 1, 2018, the Centers for Disease Control and Prevention (CDC) funds all health departments to support reporting and monitoring of these results which is referred to as Molecular HIV Surveillance (MHS).

Recently, local, state and federal public health agencies have analyzed MHS data to identify, investigate and respond to growing clusters of newly diagnosed individuals who share closely related HIV genetic sequences, referred to as molecular clusters. While current sequence analytic methods cannot conclusively infer directionality of transmission within these clusters (e.g. whether one person infected another), these methods have been used to initiate rapid public health action to investigate, characterize and/or prevent HIV transmission, such as occurred in Scott County Indiana in 2015.

Other types of HIV surveillance data, such as CD4+ cell count and HIV viral load tests, have been used for some time to target prevention efforts and collection of these results has been standard public health practice. However, unlike other now-standard surveillance data, the use of MHS data to identify linked molecular clusters raises the possibility that the public, and particularly the criminal justice system, might erroneously infer directionality of HIV transmission. Potential misinterpretation of molecular HIV

cluster information has raised concerns that acting upon these data could increase the already existing risk that people with HIV have for criminalization, stigma, discrimination, and abuse.

Anticipating the imminent expansion of the use of MHS to guide public health efforts, the TC CFAR thought that it was important to hold a consultation to discuss potential benefits, drawbacks, and ethical considerations of utilizing HIV sequence data for public health action to inform implementation of this new approach.

The consultation, with participation from local and state health departments, federal funders, researchers, bioethicists, legal scholars and advocates from both local and national HIV organizations led to recommendations in four overarching themes:

- a) Community education and engagement;
- b) Law and ethics;
- c) Public health policies and procedures; and
- d) Effectiveness and implementation research.

Understanding of existing public health and surveillance activities may be low, which could therefore lead to misunderstanding, mistrust and missteps as health departments made decisions about how best to utilize HIV sequence data to suit the needs of their local epidemics. Therefore, community education and engagement was identified as a priority that can equip individuals living with HIV and their allies to contribute fully to discussions on local implementation with local decision makers.

Law and ethics emerged as an important area of focus because people living with HIV could be at heightened legal risk if HIV sequence data were not used as intended and misinterpreted as evidence of possible violation of HIV criminalization laws and other state and local legislation. Criminal and civil laws and regulations governing the sharing of health information between public health departments and law enforcement agencies vary tremendously state-by-state. As such, meeting participants universally agreed that a critical first step was to conduct a comprehensive examination of state and local laws to determine privacy protections and safeguards of public health data

as well as health department policies and practices, in order to inform the community and guide responses of public health authorities who may receive a subpoena for a person's health records.

The need for more formal research in this area also emerged as a central recommendation to formally establish how and whether the benefits of this new approach may be realized. A strong call was made for further research to measure the population impact of targeting interventions to members of growing molecular clusters on preventing new HIV infections. Implementation research was recommended to: a) determine whether targeting growing clusters is more effective than current HIV prevention practices, and b) identify optimal implementation strategies to guide the response of health departments which are now responsible for conducting MHS. Advances in sequencing technology and analyses that allow inference of directionality of transmission may be available in the future, and the implications of those possibilities will warrant consideration by all stakeholders and ethicists.

In all, implementation of this new MHS approach in select health departments suggests it holds promise. However, this approach is still in an early implementation phase and successful scale-up efforts will require that risks identified in the consultation are adequately addressed. This would include adequately studying the potential to enhance HIV prevention, and how stakeholders may adapt to any changes in technology. Incorporating community education and input, with continual updates based on emerging scientific evidence, is essential, as is implementation with clear community-informed policies and procedures.



BACKGROUND

01

1.1

The pathway from clinical care to active HIV surveillance

Since the 1981 report of *Pneumocystis carinii* pneumonia (PCP) in five young gay men in Los Angeles by the Centers for Disease Control and Prevention (CDC)¹, public health authorities have been conducting standard disease surveillance activities to track the spread of HIV disease in the United States. In the 1980s an AIDS diagnosis at the later stage of HIV disease could be tracked through provider reports of AIDS-defining opportunistic infections and malignancies. Only after the availability of a blood test to detect HIV-1 antibodies in 1985, was it possible to monitor the causative agent itself, and thus allow public health authorities to track the disease from an earlier stage. In 1993² immune status tests (i.e., CD4 cell counts) were added to the AIDS case definition marking the beginning of the use of laboratory tests alone to define a case of AIDS. This definition expansion laid the groundwork for laboratory testing contributing to HIV surveillance. Public health efforts have evolved with the advent of earlier diagnosis of HIV, and advances in laboratory methods and treatment that improve detection and treatment.

The CDC's *2008 Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection*³ expanded the use of HIV surveillance data from solely being used to describe and monitor the epidemic, to initiating HIV prevention interventions such as partner services and facilitating program integration with other STD prevention efforts. These changes brought about new challenges to a data system that had strict national and local data sharing restrictions. To address this paradigm shift, the CDC developed guidelines⁴ to facilitate sharing and use of HIV surveillance data for public health action.

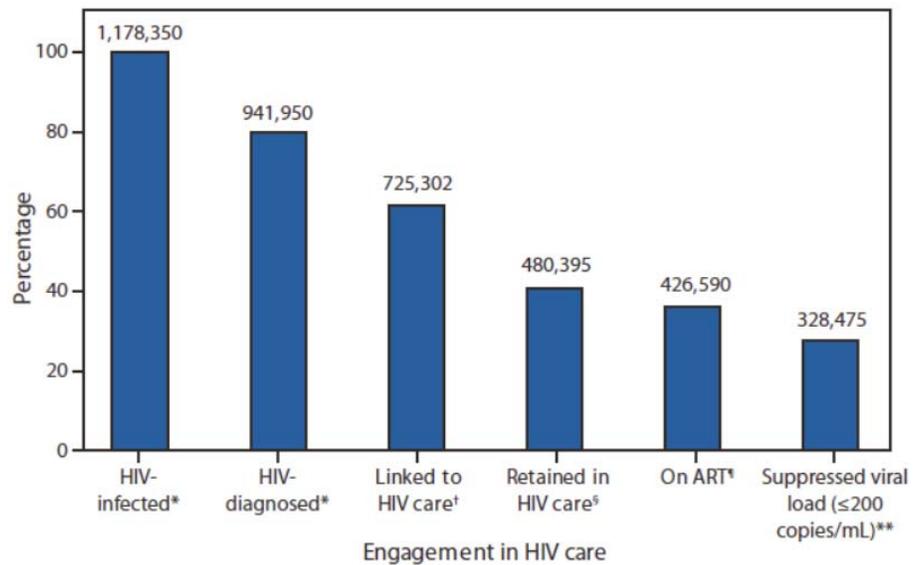
1.2

The Birth and Evolution of Data-to-Care (D2C)

The release of the National HIV/AIDS Strategy in 2010, by the office of the President's Office of National AIDS Policy, and the confirmation of the effectiveness of antiretroviral treatment as prevention (TasP⁵), suggested the need for interventions that helped ensure that people living with HIV be retained in care and virally suppressed to

reduce on-going transmission. In December of 2011, CDC published the first nationwide continuum of HIV care⁶. As shown the figure below, only 28% of the 1,178,350 people who were estimated to be living with HIV in the United States were virally suppressed.

Figure 1 Number and percentage of HIV-infected persons engaged in selected stages of the continuum of HIV care – United States, 2011



Abbreviations: HIV = human immunodeficiency virus; ART = antiretroviral therapy.
 * HIV-infected, N = 1,178,350; HIV-diagnosed, n=941,950.

These findings demanded a response, which the CDC and others moved to act upon. This led to the Data to Care (D2C) intervention which significantly expanded the use HIV surveillance data, from identifying people who may be HIV-infected through partner services to identifying people with HIV who are out of care to offer re-engagement in care and support aimed at achieving viral suppression.⁷

The CDC's D2C strategy was developed to improve engagement in care with the ultimate goal of increasing population-level viral suppression. D2C is a public health strategy that uses HIV surveillance and other data to improve outcomes for people

living with HIV along the HIV Care Continuum, by identifying persons who are in need of HIV medical care or other services and facilitating linkage to services⁷. While conceptually simple, this new use of surveillance data generated community concerns around the potential for increased stigma and breaches of privacy.

In response to these concerns, several meetings were held, including a consultation by Project Inform in 2012, to assess the acceptability and possible success of using laboratory data held by local HIV surveillance branches to find and relink people with HIV who had fallen out care. The consultation was carefully constructed to ensure a diversity of opinion about the acceptability of the active use of HIV surveillance data for this purpose, including representation of community advocates. This thoughtful process, and similar concerns, served as a model upon which to build a consultation around ethical considerations of the use of molecular HIV surveillance that led to this report.

Participants of the Project Inform consultation reached consensus that the benefit to people living with HIV, and to the public health of the community, could be sufficient to proceed with D2C activities, provided that community engagement processes took place in local jurisdictions and that proper safeguards were taken.

Since 2012, most state and directly-funded jurisdictions conduct D2C. There remain, however, structural and procedural challenges that have stymied efforts to maximize impact of the D2C approach. While D2C activities have resulted in more accurate and up-to-date surveillance databases, which can have many benefits for monitoring the epidemic, measure progress along the HIV care continuum, and accurately identify people truly out of care, the process is labor and resource intensive compared with the small number of individuals who are successfully contacted and relinked to care.

1.3

Molecular HIV Surveillance and a New Public Health Approach

The promise of molecular HIV surveillance lies in its potential to identify ongoing or emerging HIV molecular clusters, offering the possibility to efficiently direct prevention efforts toward both people at risk for HIV, and to people who are HIV-positive and not virally suppressed. Upon identification of a growing HIV cluster, primary prevention with HIV-negative individuals at high risk for infection (e.g.; reported partners of HIV cases in the cluster) can be scaled up rapidly, such as HIV testing campaigns and linkage to pre-exposure prophylaxis. For people with HIV in the cluster who are not virally suppressed at time of public health outreach following MHS cluster investigation, health department workers can ensure rapid linkage to health care and social services to support suppression efforts. For example, linkage specialists can focus their efforts on those in a cluster who are not virally suppressed (where there is an urgent need to prevent spread to additional persons). In contrast, the likelihood that an encountered individual could transmit HIV to another may be lower when health departments generate suspected out-of-care lists from applying algorithms (e.g. X period since last laboratory results) to partial or full databases of people diagnosed with HIV.

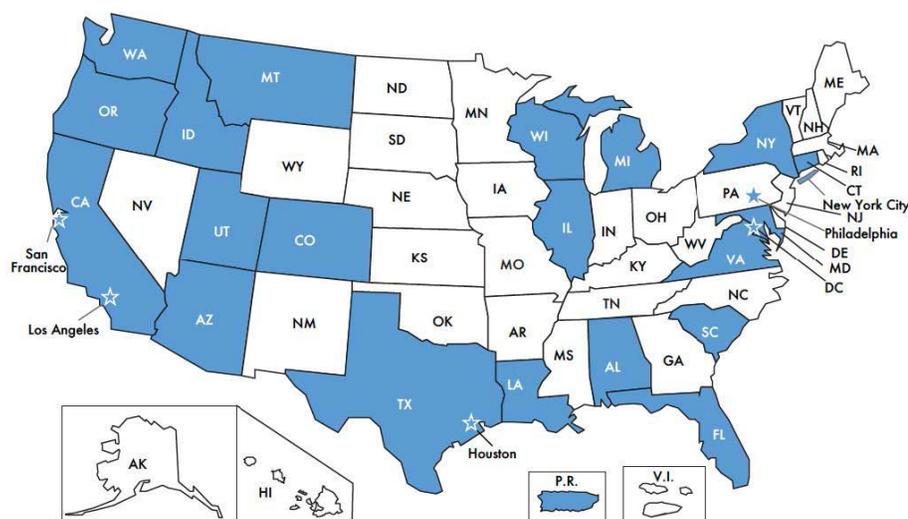
MHS analyses are possible because of HIV's high mutation rate, which results in the genetic sequence of HIV changing over time. Thus, the HIV sequences of people who are closely related by transmission, whether directly or indirectly, will be very similar, whereas HIV sequences of people who are not related by transmission will differ.

The sequence data needed for these analyses is readily available from drug resistance genotyping conducted as part of routine HIV care. HIV care guidelines recommend that health care providers order baseline genotypic HIV drug-resistance tests to guide the creation of an effective ART regimen (and at time of regimen failure), and the sequences generated through drug resistance testing are reported by laboratories to state and local health departments in participating jurisdictions.

CDC has collected HIV genetic sequence data for many years for the purposes of tracking whether, and the degree to which, drug-resistant strains of HIV were being transmitted to newly diagnosed individuals. This is a clear public health priority, as

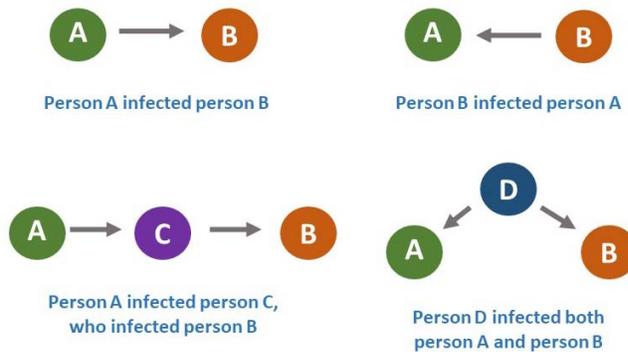
people who become infected with drug-resistant strains of HIV have fewer options to construct potent and tolerable ‘salvage’ ART regimens. During 2013–2017, 27 jurisdictions submitted resistance testing data to the CDC. However, this work expanded to all jurisdictions funded for HIV surveillance beginning in 2018.

Figure II Jurisdictions performing MHS in 2013–2017.



While it is possible to say with confidence that two individuals have strains of virus that are closely related, it is not possible to say whether one person was the source of infection for the other, using the sequences determined by current methods of resistance genotyping. In other words, experts cannot say that person “A” infected person “B” because, as indicated in Figure III: the sequence data alone are not conclusive about directionality; there could be a person “C” who was infected by “A” and then infected “B”; or a person “D” who infected both “A” and “B” and whose HIV sequence data is not in the health department MHS system.

Figure III Potential underlying transmission dynamics between two identified individuals in a cluster



Being able to construct clusters of individuals with close genetic distances to one another does allow, however, for public health departments to identify both large and persistent clusters and those that are rapidly growing, both of which can benefit from intensified public health action, particularly if the HIV sequence data are paired with other demographic and geolocation data.

There are a number of examples where the use of HIV sequence data have been used to identify molecular clusters to characterize transmission patterns and initiate a targeted public health response^{8,9,10,11,12}. One of the first examples came from British Columbia, Canada. The BC Centre for Excellence in HIV/AIDS (CFE) is responsible for conducting all HIV genotyping testing in the province and maintains an automated system for monitoring HIV transmission hotspots using phylogenetic clustering analysis. In 2014 they identified a growing molecular cluster of transmitted HIV drug resistance which initiated public health follow-up. After their public health response, most members in the cluster were virally suppressed and the cluster stopped growing.¹²

In the case of Scott County, Indiana¹⁰, local public health officials became aware of an uncharacteristic and rapid uptick in new HIV infections. The CDC was able to use HIV sequence data to identify how the new infections were clustered and were able to determine with a high degree of confidence that the majority of transmissions were occurring in injection drug users who were linked geographically and through drug-using social/sexual networks.

The presence of such concrete data allowed local and Federal public health officials, along with providers and advocates, to argue for stepped up efforts to quickly link newly infected individuals and others in their risk network with appropriate physical and mental health and substance abuse care. As well, the data were sufficiently compelling that the state ultimately granted a temporary allowance of funds for provision of clean injection equipment to drug users.

Another example illustrating how analysis of HIV genetic sequence data can inform HIV epidemiology and enhance prevention efforts was presented by the Texas Department of State Health Services and CDC at the 2017 Conference on Retroviral and Opportunistic Infections (CROI¹³). In 2016, the Texas health department and CDC staff performed investigation on a molecular cluster selected due to its rapid growth and tight geographic distribution, in a known high-risk group. The purpose of the investigation was to define the extent of the cluster and underlying risk network and prioritize intervention opportunities, among others. Their investigation found strong evidence that this cluster resulted from recent active transmission and that several cases were not virally suppressed at the time of analysis. This provides an example of how identifying a growing molecular cluster, combined with partner services, could focus and enhance HIV care linkage and other interventions to bring both treatment and prevention services to individuals faster and help reduce the spread of HIV.



02

2.1

Identifying Key Considerations

The TC CFAR held a consultation to explore critical questions around the use of HIV sequence data to conduct targeted prevention and care interventions, and make recommendations to inform principles, policies, procedures and legislation to maximize the public health benefit and minimize harm to people at-risk and living with HIV. The TC CFAR recognized that timing of the consultation was particularly significant given that the CDC had begun using HIV sequence data to identify, and respond to, growing molecular clusters in select states, and that a new funding announcement from the CDC would expand the collection and use of molecular surveillance data starting in 2018.

The TC CFAR and the consultant, Project Inform, formed a planning committee for the consultation, and conducted multiple interviews, both to aid in the selection of meeting attendees and identify key issues to be discussed at the consultation. The planning committee organized and designed the consultation to allow for in depth dialogue on the benefits and potential risk to use of MHS data, with federal, state and local leaders in HIV surveillance and public health, members of and advocates for communities impacted by HIV, and experts in HIV phylodynamics research, HIV law and policy, and bioethics.

Key Stakeholder Input

To identify the key topics for discussion at the consultation, the sponsors conducted 11 in-depth interviews with 19 stakeholders who possess the following areas of expertise:

- Community engagement and advocacy
- HIV criminal and civil law
- Biomedical and public health ethics
- Biomedical, public health and social science research
- HIV surveillance

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- HIV public health interventions
 - HIV public health capacity building

We conducted nearly a dozen interviews with subject matter experts, many of whom attended the consultation. We explored three primary areas, which were drawn from the published literature^{14, 15, 16, 17, 18}:

1. Potential problems with privacy and misuse or misunderstanding of the data.
2. Potential benefits of the use of HIV sequence data, particularly to prioritize prevention and D2C efforts.
3. Issues which should guide proper implementation and use of HIV sequence data.

The results of the interviews revealed three overarching themes to focus on at the consultation. These are clustered under the key topic areas described below.

a) Data security, confidentiality, privacy and potential for misuse

The interviewees, regardless of their areas of expertise, had concerns about the perception that HIV sequence data alone could establish whether person, “A” had infected person “B”, which is referred to as the directionality of transmission. While the incompleteness of available databases and current scientific methodology make this impossible to determine, the perception that directionality may be inaccurately inferred is, alone, a widespread concern.

Some of those most familiar with MHS technology and HIV epidemiology methods also expressed concern that molecular clusters identified in particularly narrow geographic or demographic communities might increase the likelihood that directionality could be inappropriately inferred by individuals inside or outside of the public health department. This concern highlights the need for appropriate training and protocols of those who learn of, or have access to, HIV sequence data.

One of the concerns that troubled all of the interviewees was the possibility that people with HIV living in areas of the United States where existing laws that criminalize HIV exposure or non-disclosure of HIV status (hereafter referred to as HIV criminalization) are aggressively imposed could be even more vulnerable to prosecution and imprisonment should the perception of directionality be wrongly held by prosecutors, judges and juries if cases go to trial.

b) Public health action based on HIV sequence data

Interviewees expressed ethical and practical concerns about the degree to which public health action based on sequence cluster determinations might require some level of individual or community-wide consent. Research, which is governed by ethical review, requires informed consent and special privacy protections, and is required to make every effort to identify and explain the risks of participating in such research to prospective participants. Public health action, however, does not.

Indeed, there are no requirements in many jurisdictions that individuals be informed that their private health information (e.g. CD4+ T cell and viral load test results) will be provided on a continuing basis to the public health department. Further, most states do not require that HIV test-takers be informed of the criminal laws regarding HIV disclosure or exposure. Interviewees pondered whether the heightened potential risks that come with public health use of HIV sequence data cross the threshold by which individual consent, or at least broader knowledge of such risks, is now warranted.

c) Potential benefits and risks

Interviewees indicated that there could be numerous benefits to the public health use of HIV sequence data. These include potential for near real-time tracking of HIV transmissions, which could rapidly deploy HIV prevention activities (both with those at-risk and those diagnosed with HIV). Additionally, on-going monitoring of cluster growth could be used to more precisely determine whether an intervention worked.

Consultation Agenda

Based on common themes emerging from the key stakeholder interviews, the final agenda (see Appendix 1) was developed to meet the following three aims:

1. Generate stakeholder consensus on how potential public health benefits of identifying and acting on emerging molecular clusters identified from HIV sequence data may be best achieved and evaluated;
2. Identify and make recommendations for the actions various stakeholders should take to ensure the ethical, safe, effective, and cost-effective use of this technology, as well as limitations or additional protections; and,
3. Where there is insufficient information to make a recommendation at this time, identify further actions that should take place (e.g. additional consultations or research) to allow recommendations to be made in the future.

The planning committee decided to begin the consultation by developing a common understanding of the specific topics to be discussed. These included:

- background on HIV drug resistance genotyping reporting of HIV sequences, what sequence analysis for molecular cluster identification can and cannot determine, and how MHS could potentially be used for public health action;
- laws and regulations that govern the potential prosecution of people living with HIV for non-disclosure of their diagnosis or, in rare cases transmission;
- public health ethics; and
- findings from current phylodynamics research and implications for public health action.



03

The consultation was held in Chicago on May 10–11, 2017. A total of 41 experts from multiple fields attended the consultation (see Appendix 2 for participants list, pp 30–31).

Participants agreed that there were multiple potential benefits to using HIV sequence data to identify and respond to growing molecular clusters, and that research could help determine whether these benefits (or harms) were occurring. In all, the participants identified the following potential benefits:

- By offering various prevention and care interventions to people in growing molecular clusters, public health departments could more effectively disrupt HIV transmission and result in better health outcomes for people at-risk for and living with HIV;
- By identifying growing molecular clusters, health departments could facilitate a more rapid response to unexpected threats such as the Indiana HIV outbreak;
- Through careful examination of patterns of growing molecular clusters, public health departments could identify missed prevention and care opportunities which could help guide health department staff, providers, policy makers and advocates as they seek appropriate resources;
- Ongoing monitoring of changes in molecular cluster growth could help multiple stakeholders, including health departments, AIDS service organizations, and health care clinics, to evaluate prevention interventions and improve future efforts;
- Detailed analysis of HIV sequences associated with growing molecular clusters could help public health departments detect emergence of strains that are more transmissible in general or particular social or sexual networks, such as drug-resistant viruses.

The diverse topics covered in the consultation agenda and the broad array of experts from multiple sectors of the HIV community allowed for the identification of varied themes and concerns to emerge with great clarity and for the development of insightful recommendations. Participants in the consultation acknowledged the

potential public health benefits to researcher's and health department staff's use of HIV sequence data, but they unanimously agreed that further evidence was needed to substantiate these benefits.

Given the sense of urgency to provide guidance to federal, state and local health agencies that are currently using MHS data or that plan to do so, and to those in other professions whose work could be impacted by wider use of MHS data and who should inform it, the meeting attendees made the following recommendations, either for direct action now or in the near future. These recommendations fell broadly into four categories: a) Community education and engagement; b) Law and ethics; c) Public health policies and procedures; and d) Effectiveness and implementation research.

a) Community Education and Engagement

The attendees of the consultation universally acknowledged the importance of broadly sharing knowledge and experience with multiple types of stakeholders about: molecular biology; disease surveillance; HIV criminal and civil law; public health activities, policies and procedures; community engagement; and implementation research relevant for MHS.

Although professional and ethical public health practices, universally demand education of the public, and particularly those most affected by infectious diseases, the need for education and engagement with affected communities is especially warranted when the potential harms are great or perceived to be great, regardless of the likelihood of risk.

In the course of discussions with stakeholders before, during and after the meeting, some expressed concern that people who might be most directly impacted by the use of MHS data may have little to no understanding that laboratory results ordered for the purpose of their clinical care were being reported to the public health department. Should disclosure and/or misuse of data result (there is minimal research on this topic), individuals and the communities they come from would be alarmed to know that such data were being collected for many years and used to monitor population-based HIV drug resistance, re-engage people in care, and were now being used to track emerging molecular clusters to target public health efforts.

While several participants of the consultation directly represented affected communities, all of the consultation's participants agreed that efforts were needed to incorporate the input of people living with, or at risk of acquiring, HIV into final practice recommendations regarding the use of clinical and laboratory data for public health purposes.

Participants acknowledged that significant additional efforts are required to define the scope of the needed education and engagement between health departments, community members and other advocates. There was also concern that communities most affected by HIV may be among the least likely to know about public health disease reporting and its use in prevention efforts, and that educational efforts could backfire because of lack of knowledge of the benefits and limitations of public health practice.

The participants of the consultation made the following recommendations to address these concerns:

- Conduct surveys, focus groups, and/or key-informant interviews among community stakeholders (e.g. community advocates, people living with HIV or at risk, medical providers, health department staff, researchers, policy makers, legal advocates, criminal justice system) to evaluate knowledge and understanding of public health HIV-related practices (including MHS), and elicit feedback on concerns and potential solutions to address concerns
- Use survey results to design educational materials to inform the community about the use of MHS data to guide and inform public health practice and how these data are safeguarded and protected
- Call on national organizations to play a leadership role in developing and disseminating messaging on the use of MHS data for public health practice that can serve as a model for community education, including updates as MHS successes and failures emerge over time

-
- Develop local plans, and identify effective methods, for community education, communication and engagement to inform local implementation of the public health approach to using MHS data, and ensure practice is tailored to address local policies and laws.
 - Educate researchers on the risks and benefits of the use of MHS data and optimal confidentiality/security protocols.

b) Law and Ethics

Prosecution in response to HIV criminalization laws was central to consultation participants' concerns of the use of MHS data to identify molecular clusters for public health response and echoed the concerns identified in the key informant interviews. In 2016, there were 30 states with HIV-specific laws, and nine states with what were variously called "infectious," "communicable," "venereal," or "contagious" disease laws, all of which could be used for criminal purpose against people with HIV (Figure IV¹⁹).

The potential for misinterpretation of what can be inferred from membership in molecular clusters for possible criminal prosecution poses a real risk to people living with HIV. Furthermore, even perceived danger to people living with HIV that MHS data could be used to incriminate them could deter them from seeking prevention and care services.

Consultation participants had difficulty crafting specific recommendations, given the following: variation in state law and regulations on HIV exposure and non-disclosure and, the application of such laws and regulations; geographic differences in political climate that either enhances or deters use of governmental data; current or planned efforts to change HIV criminalization laws and procedures. Thus, recommendations focused on increasing understanding of the legal and operational protections in place to safeguard surveillance data (of which MHS data are a part) against subpoenas for purposes of criminal and civil prosecutions. To strengthen data protections, it was emphasized that it was important to identify existing model laws, and examples of effective health department response to subpoenas for surveillance or other programmatic data.

posure or HIV status non-disclosure, as well as recent history of such responses, including the provision of health data or records from public health actions (such as partner notification interviews) and any compulsion of health department staff to testify in court.

- Assess the need for education of health departments' legal counsel about MHS data and its use for public health action; and the potential for harm to people living with HIV from provision of sequence data to law enforcement.
- Review existing protection laws and identify how they can be strengthened.
- Develop model laws that offer strong protection of health department data against subpoenas as well as model policies and procedures on how health departments can protect data from requests for subpoenas. Develop educational material to disseminate model laws, policies and procedures.
- Strengthen national and local advocacy for or modernizing HIV criminalization laws.

c) Public Health Policies and Procedures

The CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Data Security and Confidentiality guidelines⁴ outline standard practices to safeguard HIV surveillance data to ensure appropriate sharing and use of data for public health action. The CDC *Guidance for Detecting, Investigating, and Responding to HIV Transmission Clusters*²⁰, referred to as the Cluster Guidance hereafter, was released in March 2017, and provides further guidance on data security and sharing. Both documents offer broad guidelines to state and local health departments regarding the use and protection of surveillance data, and have a key tenet that data are shared only on a need-to-know basis. However, given that the NCHHSTP data security guidelines were developed before the advent of the use of MHS data for public health action, consultation participants thought it would be important for the CDC and health departments to specifically train staff on MHS-related activities to ensure that all

safeguards and activities are clearly explained and adhered to. They also thought that privacy protections and policies to minimize stigma and other harms should be routinely monitored through continuous evaluation and quality improvement processes. Consultation participants agreed on the need for health departments to develop methods to standardize training and assess the quality of public health staff performing analyses of, and acting on, molecular clusters.

Public health experts pointed out that the use of genetic sequence data to track the spread of disease has been in place for several decades, including tracking the spread of drug resistant bacterial diseases such as tuberculosis and community-acquired strains of Staphylococcus. Participants also noted that there were research projects utilizing HIV sequence data for public health purposes inside and outside of the United States and thought these could offer helpful guides for education, policy and evaluation. Specifically, participants developed the recommendations presented below for the federal and local public health sector.

Table 1:
Recommendations for Action by the Public Health Sector

ACTIVITY	FEDERAL	LOCAL
Conduct a literature review and analysis on the public health use of molecular surveillance data for other communicable diseases (e.g. TB, etc.) or control of disease outbreaks (e.g. food borne illnesses), and identify best practices.	X	
Conduct a literature review and key-informant interviews with researchers and health departments who have initiated activities responding to molecular clusters to identify successes and lessons learned.	X	
Conduct a review of standards of practices for the active use of laboratory data for Data to Care and partner services programs, determine the degree of fidelity to practices by various health departments and identify procedures to evaluate staff's fidelity to protocol and the acceptability of practices among affected communities.	X	X
Update national guidelines and local policies and procedures to address what data should be shared, with whom and for what purposes to ensure data security and confidentiality in the process of identifying, investigating, and responding to growing molecular clusters. The guidelines should identify a role for someone to oversee quality assurance of data privacy and protections and monitor adverse outcomes from any misuse of data by the criminal justice system	X	X
Use community input to help inform local implementation of public health interventions using HIV sequence data	X	X
Develop scripts for health department staff to use when conducting prevention interventions (e.g. partner services, and re-engagement in care) in response to growing clusters that do not stigmatize the population being served	X	X
Health departments should develop protocols on how to act on growing molecular clusters derived from MHS data that take into consideration the political environment and state laws that could increase the potential for harm to people living with HIV		X

d) Effectiveness and Implementation Research

Consultation participants agreed that more evidence is needed to determine the impact that targeting HIV prevention interventions to members of growing molecular clusters has on reducing transmissions, and whether this approach is more effective than current health department practice. More should also be learned about how to implement MHS to maximize effectiveness, especially given constrained resources at many health departments; this includes studying whether MHS can replace or prioritize existing practices. Given the limited evidence about these questions to date and concerns identified during the consultation for potential or perceived harms, participants recommended a research and evaluation agenda to build a body of evidence on benefits of, and best practices for, using HIV surveillance data as well as its risks:

- Identify and perform new methods that do not require randomized controlled trials to assess public health actions based on MHS-identified growing molecular clusters, including evaluations of:
 - effectiveness in reducing new HIV infections and/or increasing the number of people in care and virally suppressed (in comparison to current health department practices and/or when used to modify, replace, or augment current practices);
 - cost effectiveness (in comparison to current health department practices and/or when used to modify, replace, or augment current practices);
 - prioritization of scarce health department resources;
 - effects on stigma among those at risk for, or living with, HIV;
 - effects on vulnerability of people living with HIV to prosecution for HIV exposure or non-disclosure.
- Apply implementation science research to identify which interventions are most effective in reducing new HIV infections and increasing viral load suppression in response to growing HIV molecular clusters.
- Promote investment by, collaboration among, NIH, CDC and health departments to carry out these recommendations, through new and existing NIH funding opportunities.²¹

Several specific research questions that would form ideal partnerships between academic researchers and public health departments were recommended as part of the above agenda, including determining:

- whether greater use of MHS data is more effective at uncovering and targeting action to epidemiological trends than routine public health methods;
- whether cost-effectiveness or cost-savings may be achieved by using MHS data to enhance current public health efforts;
- whether there is an epidemiological benefit of using MHS data to guide a “real-time response” to growing molecular over current methods;
- if it is possible to develop an algorithm for designing, implementing and evaluating the use of MHS-guided public health action that may be used in a wide variety of jurisdictions.



04

The consultation was designed to investigate the beneficial or harmful potential of the active use of MHS-guided public health action from the point of view of diverse stakeholders, and to make recommendations, wherever possible, for actions that could be taken up in the future by those stakeholders.

Both public health experience using HIV surveillance data and phylodynamics research suggest that the use of MHS data to target HIV prevention and treatment interventions can be an important new tool to reduce on-going transmission in close to real-time. However, there is still work to be done to ensure that this new approach maximizes benefit and reduces risk to people at-risk for and living with HIV. To minimize risk, substantial efforts are needed to revoke or modernize HIV criminalization laws. To better understand the benefits, consultation participants recommended carefully designed research to assess the effectiveness and implementation of this new approach and encouraged collaborations between researchers and public health departments.

The use of MHS data to guide public health action will require additional efforts to educate critical stakeholders about its purpose, implementation, and potential for preventing new HIV transmissions. This new public health strategy brings new challenges, opportunities and promise to HIV prevention. The consultation highlighted the need for: in-depth understanding of what current technology can and can't tell us about HIV transmission using reportable resistance genotyping results; research to assess the impact of this new approach in decreasing new HIV infections; and optimal state and local policies and procedures to increase its benefit and, minimize its risk to people living with HIV.

Recommendations from the consultation map out a comprehensive, multi-sector agenda that can foster, and benefit from, collaborations between public health departments, academic institutions, community organizations, HIV providers, HIV community advocates and consumers, HIV legal and policy experts, national organizations and federal research and prevention funders. These collaborations, at the local and national level, can help ensure that this new approach is implemented to maximize safety, privacy, and confidentiality of people living with, and at risk for, HIV. The Third Coast Center for AIDS Research and Project Inform hope that the timeliness of the meeting and of this report will allow those invested in ending the HIV epidemic to better develop and utilize a new tool in the most effective and safest way possible.



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Appendix 1: Consultation Agenda

May 10 – Day One

TOPIC	PRESENTER(S)
Welcome, Agenda Review, and Presentation of Interview Findings	Nanette Benbow, David Evans
HIV public health surveillance and the National HIV/AIDS Strategy – past, present and future <ul style="list-style-type: none"> • Evolution of the use of HIV surveillance for public health action • How is molecular HIV surveillance a new tool, why are we holding this meeting? (go a little deeper here on the ethical issues at stake) 	Nanette Benbow
From concerns to consensus – how multi-stakeholder engagement advances public health <ul style="list-style-type: none"> • History of 2011 consultation • Outcomes of the 2011 consultation • Lessons learned and what can be applied here 	David Evans
Putting public health advances into practice – the successes and challenges of implementing Data to Care <ul style="list-style-type: none"> • Overview of how health departments are approaching Data 2 Care and overarching lessons thus far • Where have there been challenges? • In what way do we anticipate successes or challenges might be the same or different with cluster identification and what lessons can we bring to it? 	Natalie Cramer
History and current state of MHS and its application	
<ul style="list-style-type: none"> • How did we arrive at the idea of using molecular clusters? • What are molecular clusters and how can this information be used by public health interventions to reduce HIV transmission? • What cannot be inferred from molecular clusters? • How has the CDC used this technology thus far and what lessons have been learned? • Recommendations for handling data security, confidentiality and privacy when using MHS data 	Alexa Oster
Local use of cluster analysis – a review <ul style="list-style-type: none"> • How have health departments begun to operationalize this technology? Texas example. • What are the benefits and challenges? • What is a brief sample of the range of implementation across different jurisdictions? 	Analise Monterosso

Appendix 1: Consultation Agenda, *continued*

<p>Research use of HIV sequence and cluster analysis – findings and future applications that can inform public health</p> <ul style="list-style-type: none"> • Potential for informing public health and clinical practice and concrete examples • Privacy/security considerations when working with these data – lessons learned • Considerations when combining multiple de-identified databases with sequence data and ways to address them 	<p>Sanjay Mehta</p>
<p>Digging into the details of the science (Talk about potential scenarios for directionality)</p> <ul style="list-style-type: none"> • What does this mean about our confidence in the relationships within a cluster? • Where do data of this type reside, how are they accessed/queried by individual health departments, and how are data secured? • How does additional data (e.g. named cases through partner notification) amplify the relatedness/directionality of cluster information? • Are there new uses of existing tools or new tools coming soon and what might they mean for establishing directionality based solely on the phylogenetic data? 	<p>Nanette Benbow, David Evans, based on questions from interviews</p>
<p>Group Discussion - Evaluating Success</p> <ul style="list-style-type: none"> • Solicitation of ideas to aid in consensus building — If there are benefits to utilizing data to identify clusters, how will we know whether they have achieved the intended benefits? 	<p>David Evans</p>
<p>Legal implications for public health use of HIV sequence and molecular cluster data</p> <ul style="list-style-type: none"> • What we know and don't know about how public health and medical record data has been used broadly across HIV surveillance? • What laws are in place and what is lacking to protect surveillance data from subpoena? • What specific legal tools/factors (e.g. subpoenas, etc.) could prove more problematic or be used in unique ways with phylogenetic data? • What other factors should we keep in mind? 	<p>Carol Galletly</p>
<p>Ethical implications for public health use of HIV phylogenetic cluster data</p> <ul style="list-style-type: none"> • Traditional bioethics of communicable disease data for public health action • Emerging additions or changes to ethical considerations (e.g. social justice view) and how these might apply to the use of phylogenetic data • How does one evaluate benefits/harms from an ethical perspective? 	<p>Theodore Bailey</p>

Appendix 1: Consultation Agenda, *continued*

<p>Findings from Key Informant Interviews: The social, ethical and legal issues animating this consultation</p>	<p>Nanette Benbow, David Evans</p>
<p>Large Group Discussion:</p> <ul style="list-style-type: none"> • Round Robin – Each participant names on thing they would like to explore further in the afternoon and Day Two. • What issues should be on the table in terms of benefits and risks for discussion in the small group exercises? 	<p>Moderated by David Evans</p>
<p>Review of plans for small group exercises – have we broken them down correctly?</p>	<p>Moderated by Nanette Benbow, David Evans</p>
<p>Small Group Activity</p> <ol style="list-style-type: none"> 1. Group #1 – Expand on the potential benefits to the individual (at risk or living with HIV) and to public health from using cluster analysis for public health intervention (Nanette) 2. Group #2 – Expand on the ethical and other considerations needed to be made when acting on cluster analysis data by public health interventions, including implications of perceptions of its use (David) 3. Group #3 – Expand on security of data and the criminal, civil and privacy implications from misuse of cluster analysis for public health intervention (Dana) 	<p>Individual facilitators</p>
<p>Discussion and Consolidation</p> <p>Consolidate and reorganize benefits and risks into three separate groups for each (3 x benefits and 3x risks)</p> <ul style="list-style-type: none"> • Highly likely to occur • Somewhat likely to occur • May occur but too much is unknown 	<p>Moderated by David Evans</p>
<p>Lightning Round Prioritization/Grading</p> <ul style="list-style-type: none"> • Individual meeting participants go around to flip chart sheets categorized by the previous session to indicate prioritization of issues for further discussion on Day Two. 	<p>Moderated by David Evans</p>
<p>Discussion, wrap up and describe next steps for Day Two</p>	<p>Moderated by Nanette Benbow, David Evans</p>

Appendix 1: Consultation Agenda

May 11 – Day Two

TOPIC	PRESENTER(S)
Recap and reflections from Day One	Moderated by David Evans
Small group break out instructions	Moderated by David Evans
Small Group Activity 1. Group #1 – Generate recommendations to maximize and evaluate the potential benefits of the use of HIV cluster analysis (Dana) 2. Group #2 – Generate recommendations for public health departments to address and respond to ethical and social welfare concerns when utilizing cluster analysis data (David) 3. Group #3 – Generate recommendations for safeguarding HIV cluster data from misuse (Nanette)	
Small group report backs	Moderated by David Evans
Group Discussion to Solidify Recommendations	Moderated by David Evans
Lightning round: Recommendation strengths Go around and place vote by placing stickers keeping the following question in mind: is the recommendation strong and essential or moderate and flexible?	
Reflect on lightning round results: <ul style="list-style-type: none"> • Do we all agree with the consensus that emerged from how people used their votes? • Are there strong or mild differences of opinion? • Where there are strong splits, how might they be resolved at the national or local level? 	Moderated by David Evans
Where do we have consensus that specific benefits are possible and how they can be ensured and measured?	Moderated by Nanette Benbow, David Evans
Where do we have consensus that specific risks are possible and how they can be minimized and monitored?	Moderated by Nanette Benbow, David Evans
Building a consensus statement	Moderated by Nanette, David
Wrap up and future directions	Moderated by Nanette, David

Appendix 2: Participants

Asterisks by the names denote those who were also part of the Planning Committee.

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Ethical Considerations for a Public Health Response Using Molecular HIV Surveillance Data:

A Multi-Stakeholder Approach



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